

REMARKS

This Amendment is being filed in response to the Final Office Action of March 4, 2010. A Request for Continued Examination (RCE), along with the fees for a petition for a three month extension of time and the fees for the RCE are being filed concurrently. Applicant respectfully requests reconsideration of the subject application.

Claims 1, 3-15, 17-21, 23-24, 26-28, 30, 32-33, 35-39, 41-42, 44, 46-48 and 50-55 are pending; claims 1, 3-15, 35-39, 41-42, 44, 46-48 and 50-51 are withdrawn. Claims 22, 25 and 27 are being cancelled and claims 17-21, 23-24, 26 and 28 are being amended.

Briefly, the present application concerns a tissue anchor for providing ligamentary support between two spaced locations in the body of a patient. The tissue anchor includes a head for insertion and retention in tissue, and a base formed with an aperture adapted to receive a length of a woven or knitted tape. The aperture is associated with a locking element which can flex, and which includes a convex arcuate edge which defines, with an opposed edge of the aperture, a part annular space for receiving the woven or knitted tape. The locking element flexibly cooperates with the woven or knitted tape, when the tape is positioned in the space, to permit the tape to slide through the aperture in one direction but not the other.

The ability of the locking element to flex allows the convex arcuate edge of the locking element to cooperate with the woven or knitted tape, when the woven or knitted tape is furrowed, as it moves through the aperture in the opposite

direction to "clampingly engage" the tape between the convex arcuate edge of the locking element and the opposed edge of the aperture, as is explained at paragraphs [0057] and [0063] of US Patent Publication 20050256530 (published as originally filed). The effectiveness of this clamping action is enhanced by the "furrowing" of the tape caused by the part annular space formed between the convex arcuate edge of the locking element and the opposed edge of the aperture, particularly when tension is applied to the tape.

Thus, when the tape is positioned in the part annular space, the resultant furrowing of the tape enhances the ability of the locking element to engage with the tape to resist movement of the tape through the aperture in the opposite direction. This is best illustrated in Fig.10 of the present application.

I. Procedural Posture

In previous Amendments Applicant focused on the configuration of the head as a point of patentability. In this Amendment, Applicant is focusing on the configuration of the locking element. The Office Action of April 29, 2008 provided for restriction of the originally submitted claims into four groups. In the Response filed on June 17, 2008, Applicant elected Group II, claims 17-34, drawn to a tissue anchor comprising a base and a head, the base including an aperture being adapted to receive a length of a filamentary element and only permitting unidirectional sliding movement. The current amendments are within the scope of the election and are permitted with the filing of the RCE.

II. Support for Amendments

The following table identifies the substantive amendments to the claims and where these amendments are supported in the original application.

Claim	Amendments	Reference
17	...and an associated locking element, the locking element positioned to extend across the aperture to define a part annular space between a convex arcuate edge of the locking element and an opposed edge of the aperture...	Previous claim 18 (“the locking element positioned to extend across the aperture to define a space between the locking element and an opposed edge of the aperture”). Previous claim 22 (“the edge of the locking element has a convex arcuate configuration”). Previous claim 25 (“...the space has a part annular configuration...”).
17	...said space adapted to receive a length of a woven or knitted tape...	US Patent Publication 20050256530 paragraph [0055] (“...a tape which is formed of a knitted or woven material...”).
17	... wherein the space causes the tape to furrow when the tape is positioned through the space, and wherein the locking element is adapted to flexibly cooperate with the furrowed tape...	US Patent Publication 20050256530 paragraph [0057] and [0063] (“enhanced by the part annular configuration of the space through which the filamentary material is required to pass which causes the filamentary element to furrow in its passage through the space”).
18	... and wherein the face of the locking member proximate said one direction is formed as an inward recess of the edge.	Previous claim 27 (“...wherein the face of the locking member proximate said one direction is formed as an inward recess of the edge.”)
20	...locking element includes one face in one direction and another face in an opposite direction, and wherein the convex arcuate...	Previous claim 18 (“...locking element having one face in one direction and another face in an opposite direction...”).

III. Claim Rejections – 35 USC § 103

All of claims 17-28, 30, 32-33, 35 and 52-55 are rejected under 35 U.S.C. § 103(a). All of these claims include elements of a combination of a head with a body and an aperture and an associated locking element. More specifically, the locking element extends across the aperture and defines a part annular space between a convex arcuate edge of the locking element and an opposed edge of

the aperture. The space is adapted to receive a length of a woven or knitted tape. When the tape is positioned through the space, the space causes the tape to furrow and the locking element flexibly cooperates with the furrowed tape to permit slideable movement of the tape through the space in only one direction.

As discussed below, this combination is not taught by the cited prior art, individually or in combination.

A. Colleran in view of Thal

Claims 17-20, 23-28, 30, 32-33 and 52-55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. App. Pub. No. 2003/0088250 to Colleran et al. (“Colleran”), in view of U.S. Pat. No. 5,891,168 to Thal (“Thal”). The Office Action asserts that Colleran teaches the locking element of claim 17.

Colleran discloses a bone anchor having a body which includes a suture guiding channel (235) which includes side faces (228a, 228b) forming a distal portion which is wider than the diameter of the suture (10) and a proximal restricting portion (239) that is narrower than the diameter of the suture. The bone anchor disclosed in Colleran permits a suture (10) to be pulled through the channel (235) in a first direction while limiting movement of the suture in a second direction opposite the first direction. The side faces (228a, 228b) are lined by a series of grooves (250) which themselves include edges (253, 254) which combine with the shape of the channel (235) to “push” a suture (10) towards an apex (225) into the restricting portion (239) when the suture (10) is located in the channel (235) and pulled in the second direction.

The Examiner asserts that the grooves (250) and edges (254) of Colleran teach the locking element of amended claim 17. Applicant respectfully disagrees for the following reasons.

First, the grooves/edges (250, 254) of Colleran do not teach a locking element which is positioned to extend across an aperture to define a part annular space between a convex arcuate edge of the locking element and an opposed edge of the aperture, where the space is adapted for receiving a woven or knitted tape. Second, there is no indication in Colleran that the grooves/edges of Colleran are adapted to flexibly cooperate with a woven or knitted tape. In Colleran a suture (10) is passed through channel (235). The suture (10) of Colleran has a diameter and thus a circular cross-section. As shown in figure 4A of Colleran, channel (235) is a triangular opening. A triangular opening is consistent with the above description of a suture having a circular cross-section. Amended claim 17 requires a tape. A tape does not have a circular cross-section or a diameter. It would not be obvious for a person having ordinary skill in the art of surgical anchoring to modify the triangular opening of Colleran, meant for a suture with a circular cross-section, to create the part annular space between a convex arcuate edge and an opposed edge of amended claim 17.

Additionally, the channel of Colleran is not adapted to cause a tape to furrow when tape is positioned in the channel. The suture in Colleran, even when located in the restricting portion (239) of the channel, remains taught throughout. There is no mention of furrowing in Colleran and there is no indication of a locking element which flexibly cooperates with a furrowed tape.

Thal discloses a knotless suture anchor (72). The anchor (72) includes a suture loop (66) which passes through an opening in the anchor (72) and which is not prevented from movement therein. Thal fails to disclose or suggest an anchor which includes a locking element.

Accordingly, the combination of Colleran and Thal do not teach the locking element of amended claim 17. All of the remaining pending claims are dependent upon amended claim 17 and are not taught by the combination of Colleran and Thal for the same reasons.

B. Colleran in view of Thal, in further view of Pagedas

Claims 18-21, 23-28, 30, 32-33 and 52-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Colleran in view of Thal, in further view of U.S. Pat. No. 6,015,428 to Pagedas et al. ("Pagedas"). The Office Action asserts that Pagedas, at Figs. 1-4 and 16-17 teaches the locking element of the claims of the present application.

Pagedas discloses a self locking suture lock which includes an arrangement of tongues (36) forming a formation of slots. The tongues (36) provide a conical sectional shape arranged to provide an approach opening on a front side (32) of the lock which is larger than an exit opening on a back side (34). The tongues (36) are arranged to deflect to allow passage of a suture needle (14) and a suture thread (12) having a diameter through a suture lock opening (30) from the front side (32) to the back side (34). The arrangement of the tongues (36) prevents passage of the suture thread back through the opening

from the back side (34) to the front side (32). The suture lock opening (30) provides an opening slightly smaller in diameter than the suture thread.

Similarly to Colleran, the suture lock opening of Pagedas, which is a cross-hair shaped opening for a suture having a circular cross-section, does not teach the locking element of amended claim 17. First, amended claim 17 requires a part annular space between a convex arcuate edge of the locking element and an opposed edge of an aperture. This element is not present in Pagedas. Second, amended claim 17 requires that the part annular space is adapted to receive a length of woven or knitted tape, wherein the space causes the tape to furrow when the tape is positioned through the space. There is no mention of furrowing in Pagedas and there is no indication that the suture lock opening of Pagedas flexibly cooperates with a furrowed tape. And third, the suture lock opening of Pagedas would not operate as a one way lock for the tape of amended claim 17. The tape would be able to slide in both directions through either length of the suture lock opening (30).

Accordingly, the combination of Colleran, Thal and Pagedas does not teach amended claim 17. All of the remaining claims depend upon amended claim 17 and are not taught by the combination for the same reasons.

C. Biggs

Claims 17-19 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,599,311 to Biggs et al. ("Biggs"). The Office Action asserts that Biggs teaches the locking element of claim 17.

Biggs discloses an anchor (38) which is connected to a separate connection device (36) via cords (40, 40'). See Col. 9, lines 30 to 32. Biggs describes one embodiment of an anchor (38), with reference to Figure 14, as a V-shaped spring (138) which includes an attachment portion comprising two end portions or barbs (142). According to Biggs, the barbs (142) perform an anchoring function by wedging against the bronchial passageway to create friction or by penetrating the walls of the bronchial passageway.

Biggs does not teach the locking element of amended claim 17 for at least two reasons. First, Biggs does not teach a locking element positioned to extend across an aperture to define a part annular space between a convex arcuate edge of the locking element and an opposed edge, where the space is adapted to receive a length of woven or knitted tape so as to cause the tape to furrow, and where the locking element flexibly cooperates with the furrowed tape when positioned in the space. The self-locking mechanism of Biggs is rounded and relies on a sphere and spring lock. See Fig. 18. As shown in Fig. 18, cord 40 is taught when the self-locking mechanism of Biggs is engaged. Accordingly, Biggs does not teach "wherein the space causes the tape to furrow when the tape is positioned through the space."

Second, the self locking device taught by Biggs is remote from the anchor. As shown in Fig. 4 of Biggs, the self locking device (136) is connected to the anchors (38) by cords (40). The use of a single separate self-locking device arrangement is necessary in Biggs because, in use, plural anchors (38) are anchored within bronchial passageways of a lung, and the distance between

each anchor (38) and the separate self-locking device (136) is reduced in order to cause the lung to collapse. See Biggs, Col. 13, line 53 through Col. 14, line 28. Such a use of a single self-locking device is a different function than the present invention. It would not be obvious for a person having ordinary skill in the art of surgical anchoring to use a device like the one taught by Biggs for the purpose of the present invention.

Accordingly, Biggs does not teach the locking element of amended claim 17. All of the remaining pending claims are dependent upon amended claim 17 and are not taught by Biggs for the same reasons.

IV. Conclusion

The cited references, Colleran, Thal, Pagedas and Biggs, do not teach the present invention as claimed in amended claim 17. All of the references concern devices for locking a suture or cord with a circular cross-section. In contrast, amended claim 17 concerns a device for locking a tape. Also, amended claim 17 requires that the locking element include a convex arcuate edge which defines (with an opposed edge of an aperture) a part annular space that causes the tape to furrow when positioned through the space. This element is not found in any of the cited references. Applicants respectfully request reconsideration of the application in view the current amendments and remarks.

Payment for a petition for a three month extension of time and a RCE, for a small entity, are being submitted along with this Amendment. The commissioner is hereby authorized to charge any additional fee, or credit any overpayment, to Deposit Account No. 07-1730, Docket No. 4150-005.

Respectfully submitted,

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